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Grant D. Green
Roche Palo Alto
Patent Law Dept. M/S A2-250
3431 Hillview Avenue
Palo Alto, CA 94304

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,202,333

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,202,333, which claims the human drug product ALOXI® (palonosetron hydrochloride), a pharmaceutical composition comprising ALOXI® (palonosetron hydrochloride), and a method of using ALOXI® (palonosetron hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 2, 2006, (71 Fed. Reg. 5668), would be 2,029 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (3,565 - 111) + 302
	=	2,029 days (5.6 years)

Since the regulatory review period began December 24, 1992, before the patent issued (April 13, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 24, 1992, to and including, April 13, 1993, is 111 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,202,333

Granted:	April 13, 1993
Original Expiration Date[1]:	April 13, 2010
Applicant:	Jacob Berger et al.
Owner of Record:	Roche Palo Alto LLC
Title:	Tricyclic 5-HT_3 Receptor Antagonists
Product Trade Name:	ALOXI® (palonosetron hydrochloride)
Term Extended:	5 years
Expiration Date of Extension:	April 13, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: ALOXI® (palonosetron hydrochloride)
FDA Docket No.: 04E-0394

[1]Subject to the provisions of 35 U.S.C. § 41(b).